	Application No.	Applicant(s)
Notice of Allowability	09/056,019	TUOMANEN ET AL.
	Examiner	Art Unit
	N. M. Minnifield	1645
The MAILING DATE of this communication app All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in) or other appropriate commu (IGHTS). This application is s 3 and MPEP 1308.	this application. If not included
1. This communication is responsive to 6/29/04 and 9/13/04.		
2. The allowed claim(s) is/are <u>46-63, 66-72, 74-78, 80-83, 87</u>	'-89, 92-95, 98 and 111-122;	now renumbered 1-54 respectively.
3. The drawings filed on are accepted by the Examine	er.	
 4. ☐ Acknowledgment is made of a claim for foreign priority una) ☐ All b) ☐ Some* c) ☐ None of the: 1. ☐ Certified copies of the priority documents have 2. ☐ Certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority do International Bureau (PCT Rule 17.2(a)). * Certified copies not received: 	e been received. e been received in Application	ı No
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.	of this communication to file and the state of this application.	a reply complying with the requirements
5. A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give	itted. Note the attached EXAI	MINER'S AMENDMENT or NOTICE OF declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must (a) ☐ including changes required by the Notice of Draftspers 1) ☐ hereto or 2) ☐ to Paper No./Mail Date 25. (b) ☐ including changes required by the attached Examiner's Paper No./Mail Date attached. Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in the deposit of t	son's Patent Drawing Review S Amendment / Comment or i 84(c)) should be written on the header according to 37 CFR sit of BIOLOGICAL MATE	n the Office action of e drawings in the front (not the back) of e.1.121(d). RIAL must be submitted. Note the
Attachment(s) 1. ☑ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. ☑ Information Disclosure Statements (PTO-1449 or PTO/SB/0 Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	6. ⊠ Interview Sur Paper No./M 8), 7. ⊠ Examiner's A	lail Date <u>attached</u> . mendment/Comment tatement of Reasons for Allowance

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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kelly J. Williamson, 47179 on September 13, 2004.

- 2. Applicants' amendment filed June 29, 2004 is acknowledged and has been entered. Claims 1-45, 64, 65, 73, 79, 84-86, 90, 91, 96 and 97 have been canceled. Claims 99-110 have not been entered. Claims 71, 89 and 93 have been amended. Claims 46-63, 66-72, 74-78, 80-83, 87-89, 92-95, 98 and 111-122 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims, comments in the amendment and the Examiner's Amendment set forth below.
- 3. The application has been amended as follows:

Claims 1-45 (Cancelled)

- 46. (Currently amended) An isolated polypeptide comprising [an] <u>the</u> amino acid sequence as set forth in SEQ ID NO:5, wherein said polypeptide does not bind to choline.
- 47. (Previously presented) The isolated polypeptide of claim 46, wherein said polypeptide comprises SEQ ID NO:3.

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- 48. (Previously presented) The isolated polypeptide of claim 46, wherein said polypeptide comprises SEQ ID NO:1.
- 49. (Previously presented) The isolated polypeptide of claim 46, wherein said polypeptide comprises SEQ ID NO:24.
- 50. (Previously presented) The isolated polypeptide of claim 46, wherein said polypeptide is immunogenic.
- 51. (Previously presented) The isolated polypeptide of claim 46, wherein said polypeptide comprises an amino acid sequence having up to 475 amino acids.
- 52. (Previously presented) The isolated polypeptide of claim 51, wherein said polypeptide comprises an amino acid sequence having up to 460 amino acids.
- 53. (Previously presented) A pharmaceutical composition comprising the polypeptide of claim 46 and a pharmaceutically acceptable carrier, or diluent.
- 54. (Currently amended) An isolated polypeptide comprising [an] the amino acid sequence as set forth in SEQ ID NO:4, wherein said polypeptide does not bind to choline.
- 55. (Previously presented) The isolated polypeptide of claim 54, wherein said polypeptide comprises SEQ ID NO:22.
- 56. (Previously presented) The isolated polypeptide of claim 54, wherein said polypeptide is immunogenic.
- 57. (Previously presented) The isolated polypeptide of claim 54, wherein said polypeptide comprises an amino acid sequence having up to 475 amino acids.
- 58. (Previously presented) The isolated polypeptide of claim 54, wherein said polypeptide comprises an amino acid sequence having up to 460 amino acids.
- 59. (Previously presented) An isolated polypeptide comprising a fragment of the amino acid sequence of SEQ ID NO:24, wherein said fragment does not

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bind to choline, and comprises at least 138 consecutive amino acids of SEQ ID NO:24, wherein said polypeptide is immunogenic.

- 60. (Previously presented) An isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO:5, wherein said amino acid sequence comprises at least one to 57 amino acid substitutions, wherein said polypeptide does not bind choline, is immunogenic and said polypeptide comprises up to 398 amino acids.
- 61. (Previously presented) An isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO:3, wherein said amino acid sequence comprises at least one to 57 amino acid substitutions, and said polypeptide does not bind choline and wherein said polypeptide is immunogenic.
- 62. (Previously presented) The isolated polypeptide of claim 61, wherein said polypeptide comprises the amino acid sequence set forth in SEQ ID NO:1, wherein said amino acid sequence comprises at least one to 57 amino acid substitutions, and said polypeptide does not bind choline and wherein said polypeptide is immunogenic.
- 63. (Previously presented) The isolated polypeptide of claim 61, wherein said polypeptide comprises the amino acid sequence set forth in SEQ ID NO:24, wherein said amino acid sequence comprises at least one to 57 amino acid substitutions, and said polypeptide does not bind choline and wherein said polypeptide is immunogenic.
 - 64. (Cancelled)
 - 65. (Cancelled)
- 66. (Previously presented) The isolated polypeptide of claim 60, wherein said amino acid substitutions comprise conservative amino acid substitutions.

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67. (Previously presented) An isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO:4, wherein said amino acid sequence comprises at least one to 57 amino acid substitutions, wherein said polypeptide does not bind choline and wherein said polypeptide is immunogenic and said polypeptide comprises up to 398 amino acids.

- 68. (Previously presented) The isolated polypeptide of claim 67, wherein said polypeptide comprises the amino acid sequence set forth in SEQ ID NO:22, wherein said amino acid sequence comprises at least one to 57 amino acid substitutions, and said polypeptide does not bind choline and wherein said polypeptide is immunogenic.
- 69. (Currently amended) An isolated polypeptide comprising [an] the amino acid sequence selected from the group consisting of:
 - a) an analog of the amino acid sequence set forth in SEQ ID NO:5, wherein said polypeptide does not bind choline and is immunogenic;
 - b) an analog of the amino acid sequence set forth in SEQ ID NO:4, wherein said polypeptide does not bind choline and is immunogenic;
 - c) an analog of the amino acid sequence set forth in SEQ ID NO:11, wherein said polypeptide does not bind choline, is immunogenic, and comprise up to 328 amino acids;
 - d) an analog of the amino acid sequence set forth in SEQ ID NO:9, wherein said polypeptide does not bind choline, is immunogenic, and comprises up to 376 amino acids; and,
 - e) an analog of the amino acid sequence set forth in SEQ ID NO:10, wherein said polypeptide does not bind choline, is immunogenic and comprises up to 328 amino acids.

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70. (Currently amended) An isolated polypeptide comprising [an] <u>the</u> amino acid sequence selected from the group consisting of:

- a) a derivative of the amino acid sequence set forth in SEQ ID NO:5, wherein said polypeptide does not bind choline and is immunogenic;
- b) a derivative of the amino acid sequence set forth in SEQ ID NO:4, wherein said polypeptide does not bind choline and is immunogenic;
- c) a derivative of the amino acid sequence set forth in SEQ ID NO:11, wherein said polypeptide does not bind choline, is immunogenic, and comprise up to 328 amino acids;
- d) a derivative of the amino acid sequence set forth in SEQ ID NO:9, wherein said polypeptide does not bind choline, is immunogenic, and comprises up to 376 amino acids; and,
- e) a derivative of the amino acid sequence set forth in SEQ ID NO:10, wherein said polypeptide does not bind choline, is immunogenic and comprises up to 328 amino acids.
- 71. (Currently amended) An isolated polypeptide comprising [an] the amino acid sequence selected from the group consisting of:
 - a) the amino acid sequence set forth in SEQ ID NO:5 wherein said amino acid sequence comprises at least one to 57 amino acid substitutions and said polypeptide comprises up to 398 amino acids, does not bind choline and is immunogenic, wherein said polypeptide interacts with an antibody, said antibody is capable of interacting with a full-length CbpA polypeptide;
 - b) the amino acid sequence set forth in SEQ ID NO:4 wherein said amino acid sequence comprises at least one to 57 amino acid substitutions and said polypeptide comprises up to 398 amino acids, does not bind choline

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and is immunogenic, wherein said polypeptide interacts with an antibody, said antibody is capable of interacting with a full-length CbpA polypeptide;

- c) the amino acid sequence set forth in SEQ ID NO:11wherein said amino acid sequence comprises at least one to 57 amino acid substitutions and said polypeptide, does not bind choline and is immunogenic, and comprise up to 328 amino acids, wherein said polypeptide interacts with an antibody, said antibody is capable of interacting with a full-length CbpA polypeptide;
- d) the amino acid sequence set forth in SEQ ID NO:9 wherein said amino acid sequence comprises at least one to 57 amino acid substitutions and said polypeptide does not bind choline and is immunogenic, and comprises up to 376 amino acids, wherein said polypeptide interacts with an antibody, said antibody is capable of interacting with a full-length CbpA polypeptide;
- e) the amino acid sequence set forth in SEQ ID NO:10 wherein said amino acid sequence comprises at least one to 57 amino acid substitutions and said polypeptide does not bind choline, is immunogenic and comprises up to 147 amino acids, wherein said polypeptide interacts with an antibody, said antibody is capable of interacting with a full-length CbpA polypeptide; and,
- f) the amino acid sequence set forth in SEQ ID NO:3 wherein said amino acid sequence comprises at least one to 57 amino acid substitutions and said polypeptide, does not bind choline and is immunogenic, wherein said polypeptide interacts with an antibody, said antibody is capable of interacting with a full-length CbpA polypeptide.

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72. (Currently amended) An isolated polypeptide comprising [an] the amino acid sequence selected from the group consisting of:

- a) the amino acid sequence set forth in SEQ ID NO:5, wherein said polypeptide does not bind choline, wherein said polypeptide interacts with an antibody, said antibody is capable of interacting with a full-length CbpA polypeptide;
- b) the amino acid sequence set forth in SEQ ID NO:4, wherein said polypeptide does not bind choline, wherein said polypeptide interacts with an antibody, said antibody is capable of interacting with a full-length CpbA polypeptide;
- c) the amino acid sequence set forth in SEQ ID NO:11, wherein said polypeptide does not bind choline, is immunogenic and comprise up to 328 amino acids, wherein said polypeptide interacts with an antibody, said antibody is capable of interacting with a full-length CbpA polypeptide;
- d) the amino acid sequence set forth in SEQ ID NO:9, wherein said polypeptide does not bind choline, is immunogenic and comprises up to 376 amino acids, wherein said polypeptide interacts with an antibody, said antibody is capable of interacting with the full-length CbpA polypeptide; and,
- e) the amino acid sequence set forth in SEQ ID NO:10, wherein said polypeptide does not bind choline, is immunogenic and comprises up to 328 amino acids, wherein said polypeptide interacts with an antibody, said antibody is capable of interacting with a full-length CbpA polypeptide.

73. (Cancelled)

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- 74. (Currently amended) An isolated polypeptide comprising [an] the amino acid sequence as set forth in SEQ ID NO:11, wherein said polypeptide does not bind to choline and comprises up to 328 amino acids.
- 75. (Currently amended) An isolated polypeptide comprising [an] the amino acid sequence as set forth in SEQ ID NO:9, wherein said polypeptide does not bind to choline and comprises up to 376 amino acids.
- 76. (Previously presented) The isolated polypeptide of claim 75, wherein said polypeptide comprises SEQ ID NO:7.
- 77. (Previously presented) The isolated polypeptide of claim 74, wherein said polypeptide is immunogenic.
- 78. (Previously presented) The isolated polypeptide of claim 75, wherein said polypeptide is immunogenic.
 - 79. (Cancelled)
- 80. (Previously presented) A pharmaceutical composition comprising the polypeptide of claim 74 and a pharmaceutically acceptable carrier, or diluent.
- 81. (Currently amended) An isolated polypeptide comprising [an] the amino acid sequence as set forth in SEQ ID NO:10, wherein said polypeptide does not bind to choline and said polypeptide comprises up to 328 amino acids.
- 82. (Previously presented) The isolated polypeptide of claim 81, wherein said polypeptide comprises SEQ ID NO:23.
- 83. (Previously presented) The isolated polypeptide of claim 81, wherein said polypeptide is immunogenic.

Claims 84-86 (Cancelled)

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- 87. (Currently amended) An isolated polypeptide comprising [an] the amino acid sequence set forth in SEQ ID NO:11, wherein said amino acid sequence comprises at least one to 57 amino acid substitutions, and said polypeptide does not bind choline, is immunogenic and comprises up to 328 amino acids.
- 88. (Previously presented) The isolated polypeptide of claim 87, wherein said polypeptide comprises the amino acid sequence set forth in SEQ ID NO:9, wherein said amino acid sequence comprises at least one to 57 amino acid substitutions, and said polypeptide does not bind choline and is immunogenic.
- 89. (Previously presented) The isolated polypeptide of claim 88, wherein said polypeptide comprises the amino acid sequence set forth in SEQ ID NO:7, wherein said amino acid sequence comprises at least one to 57 amino acid substitutions, and said polypeptide does not bind choline and is immunogenic.
 - 90. (Cancelled)
 - 91. (Cancelled)
- 92. (Previously presented) The isolated polypeptide of claim 87, wherein said amino acid substitutions comprise conservative amino acid substitutions.
- 93. (Currently amended) An isolated polypeptide comprising [an] the amino acid sequence set forth in SEQ ID NO:10, wherein said amino acid sequence comprises at least one to 57 amino acid substitutions, and said polypeptide does not bind choline, is immunogenic and comprises up to 147 amino acids.

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94. (Previously presented) The isolated polypeptide of claim 93, wherein said polypeptide comprises the amino acid sequence set forth in SEQ ID NO:23, wherein said amino acid sequence comprises at least one to 57 amino acid substitutions, and said polypeptide does not bind choline and is immunogenic.

- 95. (Previously presented) A pharmaceutical composition comprising the polypeptide of claim 75 and a pharmaceutically acceptable carrier, or diluent.
 - 96. (Cancelled)
 - 97. (Cancelled)
- 98. (Previously presented) The isolated polypeptide of claim 61, wherein said amino acid substitutions comprise conservative amino acid substitutions.

Claims 99-110 (Not entered)

- 111. (Previously presented) The isolated polypeptide of claim 59, wherein said polypeptide has lectin activity.
- 112. (Previously presented) The isolated polypeptide of claim 60, wherein said polypeptide has lectin activity.
- 113. (Previously presented) The isolated polypeptide of claim 61, wherein said polypeptide has lectin activity.
- 114. (Previously presented) The isolated polypeptide of claim 62, wherein said polypeptide has lectin activity.
- 115. (Previously presented) The isolated polypeptide of claim 63, wherein said polypeptide has lectin activity.

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116. (Previously presented) The isolated polypeptide of claim 67, wherein said polypeptide has lectin activity.

- 117. (Previously presented) The isolated polypeptide of claim 68, wherein said polypeptide has lectin activity.
- 118. (Previously presented) The isolated polypeptide of claim 87, wherein said polypeptide has lectin activity.
- 119. (Previously presented) The isolated polypeptide of claim 88, wherein said polypeptide has lectin activity.
- 120. (Previously presented) The isolated polypeptide of claim 89, wherein said polypeptide has lectin activity.
- 121. (Previously presented) The isolated polypeptide of claim 93, wherein said polypeptide has lectin activity.
- 122. (Previously presented) The isolated polypeptide of claim 94, wherein said polypeptide has lectin activity.
- 4. The following is an examiner's statement of reasons for allowance: The prior art does not disclose or suggest an isolated polypeptide comprising the amino acid sequences as set forth in the claims and that this polypeptide does not bind choline and have the other characteristics as set forth in the claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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5. Claims 46-63, 66-72, 74-78, 80-83, 87-89, 92-95, 98 and 111-122 have been allowed and renumbered 1-54 respectively.

- 6. It is noted that the formal drawings are now required and that Applicant should comply with the objections to the drawings as set forth in Form 948 (Draftsperson's Notice) mailed with Paper No. 25. Applicant should make sure that the figure descriptions set forth in the specification match the formal drawings that will be submitted.
- 7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Primary Examiner

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NMM